

AO 440 (Rev. 8/01) Summons in a Civil Action

UNITED STATES DISTRICT COURT

Southern

District of

New York

STACEY HALL,

SUMMONS IN A CIVIL ACTION

V.

MERCK & CO., INC., a New Jersey corporation,

CASE NUMBER:

TO: (Name and address of Defendant)

Merck & Co., Inc. A New Jersey Corporation  
One Merck Drive  
Whitehouse Station, NJ 08889

08 CV 03504

**YOU ARE HEREBY SUMMONED** and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Tina B. Nieves  
GANCEDO & NIEVES LLP  
418 N. Fair Oaks Ave, Suite 202  
Pasadena, CA 91103  
(626) 685-9800

an answer to the complaint which is served on you with this summons, within 20 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

**J. MICHAEL McMAHON**

APR 10 2008

CLERK

DATE

(By) DEPUTY CLERK

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

In Re: Fosamax Products Liability  
Litigation:

STACEY HALL,

Plaintiff,

vs.

MERCK & CO., INC., a New Jersey  
corporation,

Defendant.

CASE NO.

**COMPLAINT**

1. Strict Liability- Failure to Warn
2. Negligence
3. Breach of Implied Warranty
4. Breach of Express Warranty
5. Deceit by Concealment
6. Negligent Misrepresentation

**DEMAND FOR JURY TRIAL**

**INTRODUCTION**

This case involves the prescription drug Fosamax, which was manufactured, sold, distributed and promoted by Defendant Merck & Co., Inc. as a treatment for osteoporosis, Paget's Disease, and other conditions. Defendant misrepresented that Fosamax was a safe and effective treatment for these conditions, when in fact the drug causes osteonecrosis and osteonecrosis of the jaw, a serious and disfiguring medical condition.

**JURISDICTION AND VENUE**

1. The jurisdiction of this Court over the subject matter of this action is predicated on 28 USC Section 1332. The amount in controversy exceeds \$75,000.00, exclusive of interest and costs. Venue in this Court is proper pursuant to 28 U.S.C. §1391 in that substantial part of the events or omissions giving rise to the claims asserted herein

1 occurred in this District, and Defendant is subject to personal jurisdiction in this District.

2 **GENERAL ALLEGATIONS**

3 2. This action is an action for damages brought by Plaintiff who suffered  
4 injury as a result of being prescribed and ingesting Fosamax. Fosamax is a prescription  
5 drug which was tested, studied, researched, evaluated, endorsed, designed, formulated,  
6 compounded, manufactured, produced, processed, assembled, inspected, distributed,  
7 marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise  
8 placed in the stream of interstate commerce by Defendant.

9 3. The injuries and damages to Plaintiff were caused by the wrongful acts,  
10 omissions, and fraudulent misrepresentations of Defendant.

11 4. At all times relevant, Defendant was engaged in the business of, or was  
12 successor in interest to, entities engaged in the business of research, licensing, designing,  
13 formulating, compounding, testing, manufacturing, producing, processing, assembling,  
14 inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for  
15 sale or selling Fosamax for the use and ingestion by Plaintiff.

16 5. At all times relevant, Defendant was authorized to do business within the  
17 state of California.

18 6. At all times relevant, the officers and directors of the Defendant named  
19 herein participated in, authorized and directed the production and promotion of Fosamax  
20 when they knew, or with the exercise of reasonable care should have known, of the  
21 hazards and dangerous propensities of the product and thereby actively participated in the  
22 tortious conduct which resulted in the injuries suffered by Plaintiff.

23 7. Plaintiff files this lawsuit within the applicable limitations period of first  
24 suspecting that Fosamax was the cause of any appreciable harm sustained by Plaintiff.  
25 Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful  
26 cause of Plaintiff's injuries at an earlier time because the injuries were caused without  
27 perceptible trauma or harm, and when Plaintiff's injuries were discovered, their cause was  
28 unknown to Plaintiff.

1           8.     Additionally, Plaintiff was prevented from discovering this information  
2 sooner because Defendant misrepresented and continues to misrepresent to the public and  
3 to the medical profession that Fosamax is safe and free from serious side effects, and  
4 Defendant have fraudulently concealed facts and information that could have led  
5 Plaintiffs to discover a potential cause of action.

### 6                                   **THE PARTIES**

#### 7           **Plaintiff**

8           9.     Plaintiff, STACEY HALL, is a citizen of the United States and a resident of  
9 Valley Head, Alabama. She took Fosamax manufactured, supplied and/or marketed by  
10 Defendant, and was injured as a result.

#### 11           **Defendant**

12          10.    Defendant MERCK & CO., INC. was and is an American pharmaceutical  
13 company, incorporated under the laws of the state of New Jersey, whose principal place  
14 of business is One Merck Drive, P.O. Box 103, Whitehouse Station, New Jersey. On  
15 information and belief, said entity does business in California, and at all times relevant it  
16 developed, manufactured, and sold Fosamax in interstate commerce and in California.

17          11.    At all times relevant, Defendant did test, study, research, evaluate, endorse,  
18 design, formulate, compound, manufacture, produce, process, assemble, inspect,  
19 distribute, market, label, promote, warn, package, advertise for sale, prescribe, sell and  
20 distribute, or otherwise place in the stream of interstate commerce, Fosamax, which was  
21 ingested by Plaintiff.

### 22                                   **FACTUAL BACKGROUND**

23          12.    The compound alendronate is marketed by Defendant as Fosamax.  
24 Fosamax is a member of the bisphosphonate class of drugs. The Food and Drug  
25 Administration approved Fosamax on September 29, 1995 for the treatment of post-  
26 menopausal osteoporosis and Paget's disease. Subsequent to FDA approval, Fosamax  
27 was widely promoted, advertised and marketed by Defendant as a safe and effective  
28 medication.

1           13. Osteoporosis is a thinning and weakening of bones through the natural  
2 process of bone remodeling. In bone remodeling, osteoclasts (bone-eroding cells) break  
3 down bone through resorption, and osteoblasts (bone-building cells) build bone back up  
4 again through bone formation. These processes usually are in balance and a stable bone  
5 mass is maintained. Osteoporosis occurs when the formation of new bone does not keep  
6 up with bone destruction and bones become weak and fragile. As a bisphosphonate,  
7 Fosamax is designed to suppresses bone resorption by inactivating bone-eroding  
8 osteoclast cells thus preserving bone density.

9           14. As osteoporosis is a common and widespread disease, the market for  
10 osteoporosis treatments is enormous. Nearly 200 million women worldwide suffer from  
11 osteoporosis – approximately one-third of women aged 60-70 and two-thirds of women  
12 over the age of 80. In the United States, approximately 44 million Americans are at risk  
13 for developing osteoporosis (approximately 55% of Americans 50 years old or older) and  
14 current estimates are that 10 million Americans currently have the disease with 34 million  
15 estimated to have low bone mass, putting them at great risk for the disease.<sup>1</sup>

16           15. Today, the “global osteoporosis market exceeds \$6 billion in annual sales,  
17 and with a rapidly graying population, it's growing 25% a year.”<sup>2</sup> Defendant commands a  
18 large share of the osteoporosis treatment market with Fosamax, the second best selling  
19 drug for the company with annual sales in excess of \$3.2 billion dollars.

20           16. According to IMS Health, more than 22 million prescriptions were written  
21 for Fosamax in 2005, up 2% from 2004.<sup>3</sup> Defendant's Fosamax continues to make IMS  
22

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23           <sup>1</sup> Statistics are from National Osteoporosis Foundation, available online at:  
24 <http://www.nof.org/osteoporosis/diseasefacts.htm>.

25           <sup>2</sup> See Business Week Online, “Rebuilding Amgen's Bones; A mass-market osteoporosis  
26 drug could help reassure antsy investors,” May 15, 2006, available online at:  
[http://www.businessweek.com/magazine/content/06\\_20/b3984089.htm?chan=search](http://www.businessweek.com/magazine/content/06_20/b3984089.htm?chan=search).

27           <sup>3</sup> See IMS Health's “Leading 20 Products by Total U.S. Dispensed Prescriptions”  
28 available online at:  
[http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_73914140\\_77250364,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_73914140_77250364,00.html).

1 Health's "Leading 20 Products by Total U.S. Dispensed Prescriptions" and it is the  
2 world's best-selling osteoporosis treatment. Defendant launched an aggressive  
3 advertising campaign for Fosamax, which paid off causing physician visits for  
4 osteoporosis to nearly double.<sup>4</sup> Capitalizing on the increased attention to osteoporosis, in  
5 2005 Defendant obtained approval for an additional drug in the Fosamax family, Fosamax  
6 Plus D, which claims to have the additional value of providing a "minimum vitamin D  
7 intake consistent with the recommended guidelines..."<sup>5</sup>

8 17. Bisphosphonates are divided into two classes of agents based on their  
9 chemical structure and molecular mechanism of action – simple bisphosphonates where  
10 there is no nitrogen functionality in their structure, and more potent nitrogen-containing  
11 bisphosphonates. Nitrogenous bisphosphonates are 10-100 times more potent at  
12 inhibiting bone resorption than simple bisphosphonates.

13 18. Fosamax is a nitrogenous bisphosphonate. It is not metabolized in humans.  
14 The presence of a primary nitrogen atom in the molecule, and the non-metabolizing  
15 nature of the compound, results in Fosamax having a terminal half-life of more than ten  
16 years, which can result in a massive cumulative dose over the multi-year dosing cycle.

17 19. In the 1990s and 2000s, medical articles and studies were published  
18 reporting the occurrence of osteonecrosis (bone death) and osteonecrosis of the jaw  
19 ("ONJ") when nitrogenous bisphosphonates were used in the treatment of cancer.  
20 Defendant knew or should have known that Fosamax, as a nitrogenous bisphosphonate,  
21 shared the mechanism of action and the adverse event profiles with similar drugs within  
22 the nitrogenous subclass.

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23  
24 <sup>4</sup> See Consumer Reports, "Free rein for drug ads? A slowdown in FDA review has left  
25 consumers more vulnerable to misleading messages", February 2003, available online at:  
26 [http://www.consumerreports.org/cro/health-fitness/drugs-supplements/drug-ads-203/overview/in](http://www.consumerreports.org/cro/health-fitness/drugs-supplements/drug-ads-203/overview/index.htm)  
[dex.htm](http://www.consumerreports.org/cro/health-fitness/drugs-supplements/drug-ads-203/overview/index.htm).

27 <sup>5</sup> See Merck and Company, Inc.'s 2005 Annual Report, Financial Section, p. 23, available  
28 online at:  
[http://www.merck.com/finance/annualreport/ar2005/pdf/Merck\\_2005\\_Financial\\_Section.pdf](http://www.merck.com/finance/annualreport/ar2005/pdf/Merck_2005_Financial_Section.pdf).

1           20. More specifically, Defendant knew or should have known that the  
2 osteoclast-inhibiting effect of Fosamax leads to cessation of bone remodeling and bone  
3 turnover, and induces cumulative ischemic changes to the human mandible (lower jaw)  
4 and maxilla (upper jaw).

5           21. Defendant knew or should have known that these properties compromise  
6 the vascular supply to the area, which reduces the ability of a minor injury or disease to  
7 heal, which, in turn, can lead to osteonecrosis and osteomyelitis (bone marrow  
8 inflammation).

9           22. ONJ is a serious medical condition that can result in significant disability  
10 such as irreversible joint collapse in the jaw. Bone death as in ONJ is typically not  
11 reversible, and consequently physicians are limited to easing patient's pain and preventing  
12 the necrosis from spreading.

13           23. After Defendant began selling Fosamax, reports of osteonecrosis, ONJ, and  
14 other dental complications among its users began to surface. The early evidence  
15 indicated that Fosamax shared the class effects of all nitrogenous bisphosphonates, yet  
16 Defendant declined to conduct further study of the risk of osteonecrosis and ONJ in  
17 Fosamax users. Rather than evaluating and verifying the safety of Fosamax with respect  
18 to ONJ, Defendant sought to broaden the uses of Fosamax, including expanding approval  
19 to Fosamax D, and sought to extend the exclusivity of the patent for Fosamax through  
20 2018.

21           24. Since the launch of Fosamax in 1995, the Food and Drug Administration  
22 ("FDA") has received a significant number of reports of osteonecrosis and ONJ among  
23 users of nitrogenous bisphosphonates in general, and Fosamax specifically. In 2004, the  
24 FDA reported the results of their review of the FDA adverse events database for  
25 bisphosphonates and concluded that the risk of osteonecrosis and ONJ was not limited to  
26 intravenous nitrogenous bisphosphonates used in the treatment of cancer, but also to  
27 Fosamax, an oral medication which shares the same mechanism of action as intravenous  
28 bisphosphonates. The FDA concluded that osteonecrosis was a class effect based on the

1 reported cases involving Fosamax.

2 25. Citing a continuing safety concern for Fosamax and intravenous  
3 bisphosphonates, the FDA recommended and stated that Fosamax should include a  
4 warning on the label to alert unsuspecting physicians and consumers of the risk of  
5 osteonecrosis. Defendant has ignored the FDA's recommendation and refused to include  
6 any type of warning for osteonecrosis on its label or otherwise to this day. Physicians  
7 continue to prescribe Fosamax without knowledge of the serious risk of osteonecrosis,  
8 and consumers continue to take the medication believing there is no such risk. Indeed,  
9 Defendant continues to defend Fosamax and downplay unfavorable findings.

10 26. At the time Plaintiff and other Fosamax consumers took the drug, there  
11 were other safer alternative treatments for their osteoporosis condition.

12 27. Defendant knew of the significant risk of osteonecrosis, and specifically  
13 ONJ, but did not adequately and sufficiently warn physicians and consumers, including  
14 Plaintiff, of the risks.

15 28. As a direct result, Plaintiff was prescribed Fosamax by her physician, and  
16 ingested Fosamax as prescribed and in a foreseeable manner for a long period of time  
17 without knowledge of its dangerous side effects. Plaintiff has suffered serious injury  
18 from the ingestion of Fosamax, and requires and will require in the future ongoing  
19 medical care and treatment.

20 29. As a direct result, Plaintiff suffered severe mental and physical pain and  
21 suffering and has sustained permanent injuries and emotional distress.

22 30. As a direct result, Plaintiff sustained economic loss, including loss of  
23 earnings and diminution or loss of earning capacity.

24 31. If Plaintiff had known the risks and dangers associated with Fosamax®,  
25 Plaintiff would not have taken Fosamax and consequentially would not have been subject  
26 to its serious side effects.

27 32. As a result of defendant's actions, Plaintiff and her prescribing physicians  
28 were unaware, and could not have reasonably known or have learned through reasonable

1 diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that  
2 those risks were the direct and proximate result of Defendant's acts, omissions, and  
3 misrepresentations.

4 **FIRST CLAIM FOR RELIEF**

5 **STRICT LIABILITY - FAILURE TO WARN**

6 33. Plaintiff incorporates by reference to all preceding paragraphs as if fully set  
7 forth herein.

8 34. Defendant is manufacturer and/or supplier of Fosamax.

9 35. The Fosamax manufactured and/or supplied by Defendant was and is  
10 unaccompanied by proper warnings regarding all possible adverse side effects associated  
11 with the use of Fosamax and the comparative severity and duration of such adverse  
12 effects; the warnings given did not accurately reflect the symptoms, scope or severity of  
13 the side effects.

14 36. Defendant failed to perform adequate testing in that adequate testing would  
15 have shown that Fosamax possessed serious potential side effects with respect to which  
16 full and proper warnings accurately and fully reflecting symptoms, scope and severity  
17 should have been made, with respect to the use of this drug.

18 37. The Fosamax manufactured and/or supplied by Defendant was defective  
19 due to inadequate post-marketing warning or instruction because, after the manufacturer  
20 knew or should have known of the risk of injury from Fosamax, it failed to provide  
21 adequate warnings to users or consumers of the product and continued to aggressively  
22 promote the product.

23 38. As the producing cause and legal result of the defective condition of  
24 Fosamax as manufactured and/or supplied by Defendant, and as a direct and legal result  
25 of the negligence, carelessness, other wrongdoing and action(s) of Defendant described  
26 herein:

27 (a) Plaintiff has been injured in health, strength and activity and suffered  
28 injuries to body and mind, the exact nature and extent of which are not known at this

1 time;

2 (b) Plaintiff sustained economic loss, including loss of earnings and  
3 diminution or loss of earning capacity, the exact amount of which is presently unknown;

4 (c) Plaintiff required reasonable and necessary health care, attention and  
5 services and did incur medical, health, incidental and related expenses. Plaintiff is  
6 informed and believes and thereon alleges said plaintiff may in the future be required to  
7 obtain medical and/or hospital care, attention, and services in an amount as yet  
8 unascertained.

9 **SECOND CLAIM FOR RELIEF**

10 **NEGLIGENCE**

11 39. Plaintiff incorporates by reference all preceding paragraphs as if fully set  
12 forth herein.

13 40. Defendant had a duty to exercise reasonable care in the manufacture, sale  
14 and/or distribution of Fosamax into the stream of commerce, including a duty to assure  
15 that the product did not cause users to suffer from unreasonable, dangerous side effects.

16 41. Defendant failed to exercise ordinary care in the manufacture, design,  
17 formulation, distribution, production, processing, assembly, inspection, marketing,  
18 labeling, packaging, preparation for use and sale of Fosamax into interstate commerce in  
19 that Defendant knew or should have known that the product Fosamax created a high risk  
20 of unreasonable, dangerous side effects, some of which, e.g. osteonecrosis and ONJ, can  
21 cause extraordinary suffering.

22 42. Defendant was negligent in the design, manufacture, testing, advertising,  
23 warning, marketing, and sale of Fosamax in that they:

24 (a) Failed to use due care in designing and manufacturing Fosamax so as  
25 to avoid the above risks to individuals when Fosamax was being used to treat  
26 osteoporosis and Paget's disease;

27 (b) Failed to accompany their product with proper warnings regarding  
28 all possible adverse side effects associated with the use of Fosamax and the comparative

1 severity and duration of such adverse effects, the warnings did not accurately reflect the  
2 symptoms, scope or severity of the side effects;

3 (c) Failed to conduct adequate pre-clinical and clinical testing and  
4 post-marketing surveillance to determine the safety of Fosamax;

5 (d) Failed to provide adequate instruction and warning to medical care  
6 providers for the appropriate use of Fosamax;

7 (e) Were otherwise careless or negligent.

8 43. Despite the fact that Defendant knew or should have known that Fosamax  
9 caused unreasonable, dangerous side effects which many users would be unable to  
10 remedy by any means, Defendant continued to market Fosamax when there were safer  
11 alternative methods of treatment.

12 44. Defendant knew or should have known that consumers such as Plaintiff  
13 would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care  
14 as described above.

15 45. Defendant's negligence was a proximate cause of Plaintiff's injuries, harm  
16 and economic loss which she suffered and will continue to suffer as previously described.

17 **THIRD CLAIM FOR RELIEF**

18 **FOR BREACH OF IMPLIED WARRANTY**

19 46. Plaintiff incorporates by reference all preceding paragraphs as if fully set  
20 forth herein.

21 47. At all times relevant herein, Defendant impliedly warranted to members of  
22 the public and health care providers that the product was of merchantable quality and safe  
23 and fit for use as a treatment for osteoporosis and Paget's disease.

24 48. Plaintiff was and is unskilled in the research, design and manufacture of  
25 Fosamax and reasonably relied entirely on the skill, judgment and implied warranty of  
26 Defendant in using the product.

27 49. At all times that Defendant marketed, sold and/or distributed Fosamax for  
28 use by Plaintiff, Defendant had actual or constructive knowledge of the particular purpose

1 for which this drug was to be used by Plaintiff.

2 50. At all times that Defendant marketed, sold and/or distributed Fosamax  
3 Defendant knew or had reason to know that Plaintiff was relying and in fact did rely on  
4 Defendant's implied warranties.

5 51. Plaintiff and her physicians reasonably relied upon the skill and judgment of  
6 Defendant as to whether Fosamax was of merchantable quality and safe and fit for its  
7 intended use.

8 52. Contrary to such implied warranty, Fosamax was not of merchantable  
9 quality or safe or fit for its intended use, because the product was and is unreasonably  
10 dangerous and unfit for the ordinary purposes for which it was used as described above  
11 and Defendant has breached its implied warranty.

12 53. As a direct and legal result of the breach of implied warranty, Plaintiff  
13 suffered and will continue to suffer damages, injury, harm and economic loss as alleged  
14 herein.

15 **FOURTH CLAIM FOR RELIEF**

16 **FOR BREACH OF EXPRESS WARRANTY**

17 54. Plaintiff incorporates by reference all preceding paragraphs as if fully set  
18 forth herein.

19 55. At all times relevant, Defendant expressly represented and warranted to  
20 Plaintiff and Plaintiff's agents and physicians, by and through statements made by  
21 Defendant or its authorized agents or sales representatives, orally and in publications,  
22 package inserts and other written materials intended for physicians, medical patients and  
23 the general public, that Fosamax was safe, effective, fit and proper for its intended use.  
24 In reliance upon said warranties, Plaintiff purchased said product.

25 56. Plaintiff, along with the general public, relied directly and indirectly, upon  
26 said express warranties made by Defendant, in connection with the use of Fosamax. Said  
27 express warranties were part of the sale of the product, in that Defendant warranted the  
28 safeness of the product.

1 57. Fosamax does not conform to these express representations because  
2 Fosamax is not safe and has high levels of serious side effects, including disfiguring and  
3 life threatening side effects.

4 58. As a direct and legal result of the breach of said warranties, Plaintiff  
5 suffered and will continue to suffer damages, injury, harm and economic loss as alleged  
6 herein.

7 **FIFTH CLAIM FOR RELIEF**

8 **DECEIT BY CONCEALMENT**

9 59. Plaintiff incorporates by reference all preceding paragraphs as if fully set  
10 forth herein.

11 60. Defendant, from the time that Fosamax was first tested, studied, researched,  
12 evaluated, endorsed, manufactured, marketed and distributed, and up to the present,  
13 willfully deceived Plaintiff by concealing from Plaintiff, Plaintiff's physicians and the  
14 general public, the true facts concerning Fosamax, which Defendant had a duty to  
15 disclose.

16 61. Defendant represented through its labeling, advertising, marketing  
17 materials, detail persons, seminar presentations, publications, notice letters, and  
18 regulatory submissions that Fosamax was safe and willfully withheld and concealed  
19 information about the substantial risks of using Fosamax.

20 62. Defendant represented that Fosamax was safer than other alternative  
21 medications and willfully concealed information which demonstrated that Fosamax was  
22 not safer than alternatives available on the market.

23 63. At all times relevant herein, Defendant conducted a sales and marketing  
24 campaign to promote the sale of Fosamax and willfully deceive Plaintiff, Plaintiff's  
25 physicians and the general public as to the health risks and consequences of the use of  
26 Fosamax. Defendant was aware of the foregoing, and that Fosamax was not safe, fit and  
27 effective for human consumption, the use of Fosamax is hazardous to health, and  
28 Fosamax has a serious propensity to cause serious injuries to users, including but not

1 limited to the injuries suffered by Plaintiff as delineated herein.

2 64. Defendant intentionally concealed and suppressed the true facts concerning  
3 Fosamax with the intent to defraud Plaintiff, in that Defendant knew that Plaintiff's  
4 physicians would not prescribe Fosamax, and Plaintiffs would not have used Fosamax, if  
5 they were aware of the true facts concerning the dangers of Fosamax.

6 65. As a result of the foregoing fraudulent and deceitful conduct by the  
7 Defendant, Plaintiff suffered injuries and damages as alleged herein.

8 **SIXTH CLAIM FOR RELIEF**

9 **NEGLIGENT MISREPRESENTATION**

10 66. Plaintiff incorporates by reference all preceding paragraphs as if fully set  
11 forth herein.

12 67. From the time that Fosamax was first tested, studied, researched, evaluated,  
13 endorsed, manufactured, marketed and distributed, and up to the present, Defendant made  
14 false misrepresentations, as previously set forth herein, to Plaintiff, Plaintiff's physicians  
15 and the general public, including but not limited to the misrepresentation that Fosamax  
16 was safe, fit and effective for human consumption. At all times relevant, Defendant  
17 conducted a sales and marketing campaign to promote the sale of Fosamax and willfully  
18 deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and  
19 consequences of the use of the product.

20 68. Defendant made the foregoing representations without any reasonable  
21 ground for believing them to be true. These representations were made directly by  
22 Defendant, by sales representatives and other authorized agents of said Defendant, and in  
23 publications and other written materials directed to physicians, medical patients and the  
24 public, with the intention of inducing reliance and the prescription, purchase and use of  
25 Fosamax.

26 69. The foregoing representations by the Defendant were in fact false, in that  
27 Fosamax was not safe, fit and effective for human consumption, the use of Fosamax is  
28 hazardous to health, and Fosamax has a serious propensity to cause serious injuries to

1 users, including but not limited to the injuries suffered by Plaintiff as delineated herein.

2 70. The foregoing representations by Defendant were made with the intention  
3 of inducing reliance and the prescription, purchase and use of Fosamax.

4 71. In reliance on the misrepresentations by Defendant, Plaintiff was induced to  
5 purchase and use Fosamax. If Plaintiff had known of the true facts and the facts  
6 concealed by the Defendant, Plaintiff would not have used Fosamax. The reliance of  
7 Plaintiff upon Defendant's misrepresentations was justified because such  
8 misrepresentations were made and conducted by individuals and entities that were in a  
9 position to know the true facts.

10 72. As a result of the foregoing negligent misrepresentations by Defendant,  
11 Plaintiff suffered injuries and damages as alleged herein.

12 **PUNITIVE DAMAGES ALLEGATIONS**

13 **(As to the First, Second, Fifth, and Sixth Claims for Relief, only)**

14 73. Plaintiff incorporates by reference all preceding paragraphs as if fully set  
15 forth herein.

16 74. The acts, conduct, and omissions of Defendant, as alleged throughout this  
17 Complaint were willful and malicious and were done with a conscious disregard for the  
18 rights of Plaintiff and other users of the Defendant's product and for the primary purpose  
19 of increasing Defendant's profits from the sale and distribution of Fosamax. Defendant's  
20 outrageous and unconscionable conduct warrants an award of exemplary and punitive  
21 damages against Defendant in an amount appropriate to punish and make an example of  
22 Defendant.

23 75. Prior to the manufacturing, sale and distribution of Fosamax, Defendant  
24 knew that said medication was in a defective condition as previously described herein and  
25 knew that those who were prescribed the medication would experience and did  
26 experience severe physical, mental, and emotional injuries. Further, Defendant, through  
27 its officers, directors, managers, and agents, had knowledge that the medication presented  
28 a substantial and unreasonable risk at harm to the public, including Plaintiff and as such,

1 said consumers of said drugs were unreasonably subjected to risk of injury or death from  
2 the consumption of said product.

3 76. Despite such knowledge, Defendant, acting through their officers, directors  
4 and managing agents for the purpose of enhancing Defendant's profits, knowingly and  
5 deliberately failed to remedy the known defects in said medication and failed to warn the  
6 public, including Plaintiff, of the extreme risk of injury occasioned by said defects  
7 inherent in Fosamax. Defendant and its individual agents, officers, and directors  
8 intentionally proceeded with the manufacturing, sale, and distribution and marketing of  
9 Fosamax knowing persons would be exposed to serious danger in order to advance  
10 Defendant's own pecuniary interest and monetary profits.

11 77. Defendant's conduct was despicable, and so contemptible that it would be  
12 looked down upon and despised by ordinary decent people, and was carried on by  
13 Defendant with willful and conscious disregard for the safety of Plaintiff, entitling  
14 Plaintiff to exemplary damages.


15 **WHEREFORE**, Plaintiff prays for judgment against Defendant as follows, as  
16 appropriate to each cause of action:

- 17 1. General damages in an amount that will conform to proof at time of trial;
- 18 2. Special damages in an amount within the jurisdiction of this Court and  
19 according to proof at the time of trial;
- 20 3. Loss of earnings and impaired earning capacity according to proof at the  
21 time of trial;
- 22 4. Medical expenses, past and future, according to proof at the time of trial;
- 23 5. For past and future mental and emotional distress, according to proof;
- 24 6. For punitive or exemplary damages according to proof on the First, Second,  
25 Fifth, and Sixth Causes of Action;
- 26 7. Attorney's fees;
- 27 8. For costs of suit incurred herein;
- 28 9. For pre-judgment interest as provided by law; and

10. For such other and further relief as the Court may deem just and proper.  
Dated: April 1, 2008

**GANCEDO & NIEVES**  
A Limited Liability Partnership

By

  
HECTOR G. GANCEDO  
TINA B. NIEVES

**Attorneys for Plaintiff**

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands trial by jury.

Dated: April 1, 2008

GANCEDO & NIEVES  
A Limited Liability Partnership

By

  
HECTOR G. GANCEDO  
TINA B. NIEVES

Attorneys for Plaintiff